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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/559,013 | 04/26/2000 | Toshiro Ono | L0461/7086(JRV) | 1882 |

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| EXAMINER |
|---|
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| ART UNIT | PAPER NUMBER |
|---|---|
| 1642 | 17 |

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

| Application No. | Applicant(s) |
|---|---|
| 09/559,013 | Ono et al |
| **Examiner** | **Art Unit** |
| Karen Canella | 1642 |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3 months* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

**Disposition of Claims** 66, 68, 69, 71, 72, 75, 76, 79, 86, 90, 97, 101, 105, 108, 113, 119

4) ☒ Claim(s) 1, 2, 6, 15, 19, 36, 38, 41, 47, 53, 54, 56, 60, 62-64 is/are pending in the application.

4a) Of the above, claim(s) 1, 2, 6, 36, 38, 47, 53, 68, 69, 71, 72 75, 79, 86, 90, 97, 101, 105, 108, 113, 119 is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *15, 19, 41, 54, 56, 60, 62-64, 66, and 76* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

**Application Papers**

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *7, 16*
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

## DETAILED ACTION

1. Acknowledgment is made of applicant election of Group VIII and SEQ ID NO:23. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 1, 2, 6, 15, 19, 36, 38, 41, 47, 53, 54, 56, 60, 62-64, 66, 68, 69, 71, 72, 75, 76, 79, 86, 90, 97, 101, 105, 108, 113, 119 are pending. Claims 1, 2, 6, 36, 38, 47, 53, 68, 69, 71, 72, 75, 79, 86, 90, 97, 101, 105, 108, 113, 119, drawn to non-elected inventions, are withdrawn from consideration. Claims 15, in part, 19, in part, 41, 54, 56, 60, 62-64, 66 and 76 are examined on the merits.

### *Claim Rejections - 35 USC § 112*

3.The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 54, 56, 60, 64 and 66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 reads "a pharmaceutical preparation comprising an agent which ....enriches selectively the presence of complexes of an MHC molecule and a human cancer associated antigen". It is not clear if the preparation comprises factors which upregulate MHC in addition to human cancer associated antigens, or if the preparation is intended to function solely by increasing the abundance of the human cancer associated antigen available to be displayed in the context of a MHC molecule. For purpose of examination it will be assumed that the preparation is intended to function solely by increasing the abundance of the human cancer associated antigen available to be displayed in the context of a MHC molecule.

Claim 54 is drawn to an isolated nucleic acid comprising a NA Group 3 molecule. The specification defines a NA Group 3 molecule on page 14 as "(a) previously unknown nucleic acids

coding for cancer associated antigen precursor". Claim 56 includes the proviso that "the fragment includes a sequence which is not identical to any sequence selected from the sequence group consisting of (1) sequences having the GenBank Accession numbers of Table 8, (2)complements of (1) and fragments of (1) and (2)". Firstly, it is not clear if the proviso encompasses both parts (a) and (b) or only part (b) of the claim. For purpose of examination, the proviso will be applied to both parts (a) and (b). Secondly, claim 56 relies on sequences defined by GenBank accession numbers which are known to be updated and thus changed with time. Thus, the claim is rendered indefinite by reference to an object that is variable. Further, the both claim 54 and 56 rely on negative limitations in an attempt to define the invention in terms of what it was not, rather than pointing out the invention. Thus claims 54 and 56 are rendered indefinite by exclusion of what the applicant did not invent rather that by pointing out what the applicant did invent. In addition, claim 56 is rejected as prolix as table 8 encompasses at least 2000 sequences. As the recitation of negative limitations is unreasonably long, and not in a format conducive to the application of a search algorithm, the metes and bounds of the claim cannot be determined.

Claim 56 recites "a fragment of a nucleic acid molecule having a nucleotide sequence of SEQ ID NO:23 of sufficient length to represent a unique sequence within mouse of human genomes, and identifying a nucleic acid encoding a cancer associated antigen precursor". The claim is missing an active method step defining the identification of the cancer associated antigen precursor.

Claims 15, 41, 54, 62, and 76 are rendered vague and indefinite in the recitation of NA Group 1, 2 or 3 molecules which comprise non-elected SEQ ID Nos.

Claim 56 is rendered vague and indefinite in the recitation of non-elected SEQ ID NO:9, 13, 15, 17 and 19.

### *Claim Rejections - 35 USC § 102*

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 15, 19, 41, 54, 56, 60, 62, 64, 66 and 76 are rejected under 35 U.S.C. 102(b) as being anticipated by Jacobs et al (WO 98/45437) as evidenced by Accession number AAV88163.

Claim 15 is drawn to a pharmaceutical composition comprising a polynucleotide and an adjuvant, when administered to the subject selectively enriches the presence of a cancer associated antigen and a MHC molecule, wherein the cancer associated antigen is a fragment of a nucleic acid molecule comprising NA Group I. Claim 19 embodies the polynucleotide of claim 15 operably linked to a promoter and a host cell comprising the isolated polypeptide of claim 15. Claim 41 is drawn to a pharmaceutical composition comprising an isolated nucleic acid molecule selected from the group consisting of NA Group 1 molecules and NA Group 2 molecules and a pharmaceutically acceptable carrier. Claim 54 is drawn to an isolated nucleic acid molecule comprising a NA group 3 molecule. Claim 56 is drawn in part to a fragment of a nucleic acid molecule having a nucleotide sequence of SEQ ID NO:23 of sufficient length to represent a unique sequence within mouse of human genomes. Claim 60 specifically embodies expression vectors comprising the isolated nucleic acid of claim 54. Claim 62 is drawn to an expression vector comprising a Na Group 1 molecule or a NA group 2 molecule and a nucleic acid encoding a MHC molecule. Claim 64 specifies a host cell comprising the expression vector of claim 60. Claim 66 is drawn to the host cell of claim 60 further comprising a nucleic acid encoding an MHC molecule. Claim 76 is drawn to a kit for the detection of the expression of a cancer associated antigen precursor comprising a pair of isolated nucleic acids consisting essentially of a 12-32 contiguous nucleotides of any of the Group I molecules and complements of the group I molecules wherein the contiguous segments are non-overlapping. Jacobs et al disclose a fragment of the Group I molecule SEQ ID NO:23 having substitutions and deletions thereof and encoding a cancer associated antigen and pharmaceutical compositions comprising expression vectors directing the expression of the disclosed polynucleotide and host cells comprising said expression vectors. (page 69, lines 14-25, page 59, line 28 to page 60, line 3). Jacobs et al teach a host cell

further comprising a nucleic acid encoding an MHC molecule (page 69, line 29 to page 70, line 3). Jacobs et al disclose kits comprising non-overlapping primers for SEQ ID NO:23 for PCR detection (page 63, lines 18-26 and page 64, lines 15-16). The specification defines NA group 1 molecules as nucleic acids selected from the group consisting of (a), (b), (c) and (d), with part (b) being defined as deletion additions and substitutions which code for a respective cancer associated antigen precursor. Jacobs et al is applied to part (b) of this definition as the sequence disclosed by Jacobs et al has deleted nucleic acid residues and substituted nucleic acid residues in relation to SEQ ID NO:23. The specification defines NA group 2 as fragments of NA group I which encode a polypeptide which binds a MHC molecule to form a complex recognized by an autologous antibody or lymphocyte. As Jacobs et al teach a B lymphocyte expressing the polypeptide encoded by the disclosed nucleic acid in the context of an MHC molecule, Jacobs et al is applied to Na Group 2 molecules. The specification teaches that NA Group 3 molecules are a subset of Na Group 1 molecules where the nucleotide sequences are selected from the group consisting of (a), (b), (c) and (d), where part (b) is defined as deletions, additions and substitutions which code for a respective cancer associated antigen precursor. Jacobs et al is applied to part (b) of this definition as the sequence disclosed by Jacobs et al has deleted nucleic acid residues and substituted nucleic acid residues in relation to SEQ ID NO:23.

7. Claims 54, 56, 60 and 64 are rejected under 35 U.S.C. 102(b) as being anticipated by Accession Numbers AI024421 as evidenced by Ono et al (PNAS, 2001, vol. 98, pp. 3282-3287).

Claim 54 is drawn to an isolated nucleic acid molecule comprising a NA group 3 molecule. Claim 56 is drawn in part to a fragment of a nucleic acid molecule having a nucleotide sequence of SEQ ID NO:23 of sufficient length to represent a unique sequence within mouse of human genomes. Claim 60 specifically embodies expression vectors comprising the isolated nucleic acid of claim 54. Claim 64 specifies a host cell comprising the expression vector of claim 60. The specification defines NA Group 3 molecules as a subset of Na Group 1 molecules where the nucleotide sequences are selected from the group cosisting of (a), (b), (c) and (d), where part (b) is defined as deletions, additions and substitutions which code for a respective cancer associated

antigen precursor and part (d) is defined as complements of part (b). Accession Number AI024421 is applied to part (d) of this definition as the disclosed sequence is the complement of a sequence that has deleted nucleic acid residues in relation to SEQ ID NO:23. Accession Number AI024421 does not specifically state that the disclosed nucleic acid is the complementary sequence of a fragment of a nucleic acid encoding a cancer associated antigen precursor. However, the disclosed human sequence was identified as being similar to the SP32 precursor. Ono et al discloses that the human SP32 precursor is a human cancer/testis antigen. Therefore, AI024421 has the inherent property of a cancer associated antigen precursor.

***Conclusion***

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.
Patent Examiner, Group 1642
May 5, 2002

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